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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Craig Heacock, et al.

Application No.: 10/616,776

Filing Date: July 10, 2003

For: MODAFINIL PHARMACEUTICAL COMPOSITIONS

Confirmation No.: 1994

Group Art Unit: 1615

Examiner: Not Yet Assigned

DATE OF DEPOSIT:

July 15, 2005

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Elizabeth A. McLoud

TYPED NAME: Elizabeth A. McLoud

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Commissioner for Patents
P.O. Box 1450
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Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).



In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **\$180.00** as set forth in § 1.17(p).

- ☒ Copies of reference numbers **21 – 49 and 63 - 71** listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of reference numbers **50 - 62** on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(i).

- ☐ Copies of references - are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number , filed for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

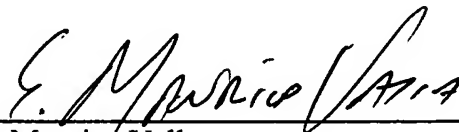
☐ The relevance of those listed references which are not in the English language is as follows:

There are no listed references which are not in the English language.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date:

7/15/05



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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. CEPH-2249/ CP241	Application No. 10/616,776
		Applicant Craig Heacock, et al.	
		Filing Date July 10, 2003	Group 1615
		Confirmation No. 1994	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	21	Becue T. et al., "Confirmation of the Structure of By-Products in the Synthesis of Modafinil by Liquid Chromatography-Mass Spectrometry," <i>J. of Chromatography</i> , 1991 , 557, 489-494	
	22	Carlson, R.F., et al., "Efficacy and safety of reformulated, micronized glyburide tablets in patients with non-insulin-dependent diabetes mellitus: a multicenter, double-blind randomized trial," <i>Clin Ther</i> , 1993 , 15(5), 788-796	
	23	Drabowicz J. et al., "A convenient procedure for the oxidation of sterically hindered sulfides to sulfoxides," <i>Synthesis</i> , 1990 , 937 – 938	
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	25	<i>Drugs of the Future</i> ; "Modafinil," 1990 , 15(2), 130-132	
	26	FDA/CDER guidance document "Dissolution Testing of Immediate Release Solid Oral Dosage Forms," 1997 , 1-11, A-1 – A-2	
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	30	Hargrove, J.T., et al., Absorption of oral progesterone is influenced by vehicle and particle size," <i>Am. J. Obstet. Gynecol.</i> , 1989 , 948-951	
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	31	Hörter D., et al., "Influence of Physicochemical Properties On Dissolution Of Drugs In The Gastrointestinal Tract," <i>Adv Drug Deliv Rev</i> , 2001 , 46(1-3), 75-87	
	32	Keese, R. et al. <i>Fundamentals of Preparative Organic Chemistry</i> 1982, Ellis Horwood Ltd., XP002310738 pp. 18-20	
	33	Kondo, N., et al., "Pharmacokinetics of a micronized, poorly water-soluble drug, HO-221, in experimental animals," <i>Biol Pharm Bull</i> , 1993 , 16(8), 746-800	
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	40	Ravin, L.J., "Preformulation," <i>Remington's Pharmaceutical Sciences</i> , 16 th Ed., 1980 , Chapter 75, 1355-1368	
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	43	Roze C., et al., "Drug CRL 40 028-Induced Inhibition of Pancreatic Secretion in Rats," Arch Int Pharmacodyn, 1983, 265, 119-127	
	44	Shah V.P. et al., "In Vitro Dissolution Profile Comparison – Statistics and Analysis of the Similarity Factor, f ₂ ," Pharmaceutical Research, 1998, 15(6), 889-896	
	45	Sheperd, J., "The fibrates in clinical practice: focus on micronised fenofibrate," Atherosclerosis, 1994, 110(Suppl), S55-S63	
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	47	Treffel, P., et al., "A new micronized 5-methoxypsoralen preparation," Acta Derm Venerol, 1992, 72, 65-67	
	48	Wadke D.A., et al., "Preformulation testing," Pharmaceutical Dosage Forms: Tablets, 2 nd Ed., 1989, 1-73	
	49	Wilson et al., Textbook of Organic Medicinal and Pharmaceutical Chemistry, 6 th Ed., J.B. Lippincott Company, 1971, 386-387	
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	51	4,122,157	10/24/78	Huber	424	21
	52	4,196,188	04/01/80	Besins	424	37
	53	4,332,721	06/01/82	Bernini	260	239.57
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	62	2004/0105891	06/03/04	Bentolila et al.	424	489
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FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	63	WO 94/21371 A1	09/29/94	PCT	X abstract	
	64	WO 95/00132 A1	01/05/95	PCT	X abstract	
	65	WO 95/01171 A1	01/12/95	PCT	X abstract	
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